General

Guideline Title

The management of vulval skin disorders.

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of vulval skin disorders. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Feb. 23 p. (Green-top guideline; no. 58). [83 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Classification of evidence levels (1++ to 4) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

What Information Needs to Be Included in History Taking and Examination When Women Are Referred to the Gynaecology Clinic with Symptoms and/or Signs of a Vulval Skin Disorder to Aid Investigation and Management?

C - The history should include details of any personal or family history of autoimmune conditions.

C - The history should include details of any personal or family history of atopic conditions (hay fever, asthma, eczema).

D - The history should include any symptoms of urinary or faecal incontinence.

Which Investigations Are Useful in the Investigation of a Woman with a Vulval Skin Disorder?

D - In the initial assessment of a woman with vulval symptoms, consider testing for thyroid disease, diabetes and sexually transmitted infections if clinically indicated.

D - Skin biopsy is not necessary when a diagnosis can be made on clinical examination. Biopsy is required if the woman fails to respond to treatment or there is clinical suspicion of vulvar intraepithelial neoplasia (VIN) or cancer.

C - Women suspected of having lichen sclerosus or lichen planus should be investigated for other autoimmune conditions if there are clinical

symptoms or signs.

C - Serum ferritin should be checked in women with vulval dermatitis.

What Is the Role of Skin Patch Testing in the Investigation and Management of Women with Vulval Dermatoses?

D - Skin patch testing should be performed for women seen with vulval dermatitis.

How Should Lichen Sclerosus and Lichen Planus Be Managed?

C - Ultrapotent steroids are important in the management of women diagnosed with lichen sclerosus and lichen planus. The patient and her general practitioner require clear advice on the management regime (Appendix 6 in the original guideline document describes a suitable management regime).

D - Approximately 4% to 10% of women with anogenital lichen sclerosus will have symptoms that do not improve with topical ultrapotent steroids (steroid-resistant disease). The recommended second-line treatment is topical tacrolimus under the supervision of a specialist clinic.

D - Surgery and CO_2 laser vaporisation are not recommended for the treatment of symptoms of lichen sclerosus. However, these treatments have a role in restoring function impaired by agglutination and adhesions such as urinary retention or narrowing of the vaginal introitus that affect sexual function or body image.

How Should VIN Be Managed?

C - The gold standard for the treatment of VIN is local surgical excision.

D - Women undergoing surgical excision of VIN should have access to reconstructive surgery.

B - Non-surgical treatments are accepted as an alternative to surgery, but women require regular, long-term follow-up.

What Non-specific Measures and Advice Are Useful in the Control of Vulval Symptoms?

D - A key part of management is general care of the vulval skin and avoidance of any potential irritants that may worsen vulval irritation.

Emollients are widely recognised as having a key role in protecting the skin and restoring skin barrier function. General vulval care includes avoiding potential irritants that may worsen vulval symptoms. Uncontrolled studies have shown that these measures reduce symptoms and resolve contact dermatitis and lichen simplex chronicus. Vulval skin is sensitive and may react both to irritants and to allergens. Irritants are commonly encountered and include underwear, sanitary protection, textile dyes, soaps and detergents (see Appendix 3 in the original guideline document). Avoiding soap and detergents and using soap substitutes can be soothing and protective to the skin. The combined use of emollients and soap substitutes helps maintain symptom relief and is safe and inexpensive. A small, prospective, open trial of maintenance with an emollient following steroid therapy showed that a proportion of women can maintain symptom relief and reduce the use of topical corticosteroids. [Evidence level 3]

Do Women with Vulval Skin Disorders Need to Remain Under Long-Term Surveillance at the Gynaecology Clinic?

C - Women with VIN need to be seen on a regular basis for vulvoscopy or careful clinical assessment and biopsy of any suspicious area.

C - Women who have been treated for VIN are at risk of intraepithelial neoplasia at other sites. Colposcopy examination should be available at follow-up.

How Should Sexual Problems Associated with Vulval Skin Disorders Be Identified and, if Identified, What Is the Most Effective Approach to Their Management?

D - Women should be asked about the impact of their vulval disorder on sexual function and appropriate advice and care should be available.

What Is the Role of Self-Examination and What Information Should Women Be Given on This?

D - Women with vulval symptoms should be encouraged to perform self-examination to monitor their skin condition and any suspicious areas.

What Training Should General Gynaecologists Have in the Management of Vulval Disorders?

D - According to the Royal College of Obstetricians and Gynaecologists (RCOG) core curriculum, obstetrics and gynaecology trainees must have knowledge and experience of the management of common vulval disorders as a training requirement.

What Is the Most Effective Model for Care Provision for the Investigation and Management of Women with Vulval Skin Disorders?

D - Women with complex or rare vulval skin disorders or who do not respond to standard treatment should be seen at a specialist vulval clinic.

Women who have difficulty with symptom control should be referred to a specialist clinic. This includes women who require frequent or prolonged use of ultrapotent topical steroids. Such women may require additional support to use first-, second- or third-line therapy. They require biopsy of any suspicious or resistant areas. [Evidence level 4]

Definitions:

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Vulval skin disorders, including dermatitis, lichen simplex, vulval candidiasis, lichen sclerosus, lichen planus, and vulvar intraepithelial neoplasia

(VIN)

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Allergy and Immunology

Dermatology

Family Practice

Obstetrics and Gynecology

Oncology

Plastic Surgery

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To review the diagnosis and management of common vulval dermatoses seen in general gynaecological practice and the role of specialist training and support

Target Population

Adult women with symptoms and/or signs of vulval skin disorders

Interventions and Practices Considered

Diagnosis/Evaluation

1. Patient history (personal, medical, drug, family)
2. Assessment of signs and symptoms
3. Testing for thyroid disease, diabetes, and sexually transmitted infections if clinically indicated

4. Skin biopsy
5. Investigation for other autoimmune diseases in women with lichen planus or lichen sclerosus
6. Serum ferritin levels
7. Skin patch testing

Treatment/Management

1. Topical ultrapotent steroids (e.g., clobetasol propionate)
2. Topical calcineurin inhibitors (tacrolimus, pimicrolimus)
3. Surgery and carbon dioxide laser vaporisation
4. Local surgical excision for vulvar intraepithelial neoplasia (VIN)
5. Reconstructive surgery
6. Non-surgical alternative treatment (topical imiquimod cream, cidofovir, laser therapy)
7. Avoidance of irritants
8. Use of emollients and advice on care of vulval skin
9. Long-term surveillance and follow-up
10. Advice and referral on sexual problems
11. Encouragement of patients on self-examination
12. Training of general gynaecologists in the management of vulval disorders
13. Specialist referral

Major Outcomes Considered

- Incidence of vulval skin disorders
- Resolution of symptoms
- Response rate
- Relapse rate
- Incidence of squamous cell cancer
- Accuracy and specificity of diagnosis

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Cochrane Library and the Cochrane Register of controlled trials were searched for relevant randomised controlled trials, systematic reviews and meta-analyses. A search of Medline from 1980 to January 2010 was also carried out. The database was searched using the MeSH terms 'pruritus vulvae', 'lichen simplex', 'lichen sclerosus', 'lichen planus', 'vulva and dermatosis', 'vulva and candidiasis', 'vulva and disease and diagnosis' and 'vulvar intraepithelial neoplasia', including all subheadings. This search was combined with a keyword search using the terms 'disease and diagnosis' and limited to 'English language and women and humans'. Databases searched were the Cochrane Database of Systematic Reviews, DARE, EMBASE, Medline, PubMed, the National Library of Health and the National Guideline Clearinghouse. Other related guidelines were available from the British Association of Sexual Health and HIV, the National Institute for Health and Clinical Excellence, the Association of Physicians in Obstetrics and Gynecology and the British Association of Dermatologists.

The definition of the type of review used in this guideline was adult women referred to secondary care with symptoms and/or signs of vulval skin disorders, and the interventions to be studied were specified as the role of history taking, examination and investigations in the diagnosis and management of vulval skin disorders, the use of ultrapotent steroids and alternatives in vulval dermatoses and the provision of surveillance in secondary care for women with vulval disorders.

The research questions were developed and submitted for peer review.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Two independent reviewers assessed the literature generated by the review to identify recommendations and the supporting evidence.

Reviewing and Grading of Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html). An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2–) will be

excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality RCTs when higher-quality observational evidence is available.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improved accuracy of diagnosis and the implementation of adequate and appropriate treatment for vulval skin disorders

Potential Harms

- Use of calcineurin inhibitors in anogenital lichen sclerosus is off-licence and should only be undertaken in a specialist clinic. The long-term safety of topical calcineurin inhibitors is not established; however, based on reports of extensive use, safety would appear to be low. While awaiting long-term data, use for longer than 2 years is not recommended owing to concerns about potential malignant transformation.
- Adverse effects of imiquimod cream include pain, erythema and swelling and can result in non-compliance.
- Primary closure following excision of small lesions of vulvar intraepithelial neoplasia (VIN) can produce good results without tension, scarring or disruption to normal anatomy. However, with larger lesions, multifocal lesions or certain anatomical sites, scarring and tension can result in pain and psychosexual morbidity. It is important that women are offered reconstructive surgery.

Qualifying Statements

Qualifying Statements

- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.
- The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and

gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that RCOG guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of vulval skin disorders. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Feb. 23 p. (Green-top guideline; no. 58). [83 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Feb

Guideline Developer(s)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

Guideline Committee

Guidelines Committee

Composition of Group That Authored the Guideline

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Peer Reviewers: British Society for the Study of Vulval Disease; RCOG Consumers' Forum; Faculty of Sexual and Reproductive Health; Lichen Sclerosus Support Group and the Vulval Health Awareness Campaign; Vulval Pain Society; Dr SE Barton FRCOG, London; Dr DL Bisson FRCOG, Bristol; Mrs A Diyaf MRCOG, Birmingham

Guidelines Committee Lead Peer Reviewers: Dr A Thomson MRCOG, Glasgow, Scotland; Mrs C Overton FRCOG, Bristol; Dr NA Siddiqui FRCOG, Glasgow, Scotland

Financial Disclosures/Conflicts of Interest

Declaration of interests: None declared.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .

Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the Royal College of Obstetricians and

Gynaecologists (RCOG) Web site.

- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the RCOG Web site.
- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the RCOG Web site.
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the RCOG Web site.

The following is also available:

- Vulval disease. Advanced training skills module. Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Aug. 6 p. Available in Portable Document Format (PDF) from the RCOG Web site.

In addition, recommendations for audit are available in section 15 of the original guideline document.

The appendices of the original guideline document contain various resources, including an executive summary, a description of common vulval skin disorders, and an example of a patient questionnaire.

Patient Resources

Patient information on general care of vulval skin is available in Appendix 3 and information on the use of clobetasol propionate 0.05% cream or ointment is available in Appendix 6 of the original guideline document.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 26, 2012.

Copyright Statement

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Readers with questions regarding guideline content are directed to contact the guideline developer.